

Claims

What is claimed is:

1. A pharmaceutical dosage form comprising an immediate release and a controlled release component,

wherein said immediate release component and said controlled release component each comprises an AAAD inhibitor and levodopa in a ratio of from about 1:1 to about 1:50;

wherein said immediate release component exhibits an *in vitro* dissolution profile comprising at least about 10% levodopa release after 15 minutes and at least about 60% levodopa release after 1 hour;

and wherein said controlled release component exhibits an *in vitro* dissolution profile comprising from about 10% to about 60% levodopa release after 1 hour, from about 20% to about 80% levodopa release after 2 hours, and at least about 30% levodopa release after 6 hours.

2. A pharmaceutical dosage form according to claim 1 wherein said dosage form further comprises a COMT inhibitor.
3. A pharmaceutical dosage form according to claim 1 wherein said AAAD inhibitor is carbidopa.
4. A pharmaceutical dosage form according to claim 1 wherein said levodopa is in the form (-)-L- α -amino- β -(3,4-dihydroxybenzene) propanoic acid, 3-hydroxy-L-tyrosine ethyl ester, phenylglycine, or a mixture thereof.
5. A pharmaceutical dosage form according to claim 1 wherein said dosage form exhibits an *in vivo* plasma profile comprising a levodopa release peak from about 6 minutes to about 6 hours after administration to a fasting patient.

6. A pharmaceutical dosage form according to claim 1 wherein said dosage form exhibits an *in vivo* plasma profile comprising a levodopa release peak from about 6 minutes to about 5 hours after administration to a fasting patient.
7. A pharmaceutical dosage form according to claim 2 wherein said dosage form exhibits an *in vivo* plasma profile comprising a COMT inhibitor release peak from about 6 minutes to about 6 hours after administration to a fasting patient.
8. A pharmaceutical dosage form according to claim 2 wherein said dosage form exhibits an *in vivo* plasma profile comprising a COMT inhibitor release peak from about 6 minutes to about 5 hours after administration to a fasting patient.
9. A pharmaceutical dosage form according to claim 2 wherein said dosage form comprises up to about 1000 mg COMT inhibitor.
10. A pharmaceutical dosage form according to claim 2 wherein said dosage form comprises from about 20 mg to about 500 mg COMT inhibitor.
11. A pharmaceutical dosage form according to claim 2 wherein said dosage form comprises from about 50 mg to about 500 mg COMT inhibitor.
12. A pharmaceutical dosage form according to claim 2 wherein said dosage form comprises from about 100 mg to about 200 mg COMT inhibitor.
13. A pharmaceutical dosage form according to claim 2 wherein said COMT inhibitor is contained only within said immediate release component.
14. A pharmaceutical dosage form according to claim 2 wherein said COMT inhibitor is contained only within said controlled release component.
15. A pharmaceutical dosage form according to claim 2 wherein said COMT inhibitor is contained within both said immediate release and said controlled release components.

16. A pharmaceutical dosage form according to claim 3 wherein said immediate release component comprises carbidopa and levodopa in a ratio of from about 1:1 to about 1:10.
17. A pharmaceutical dosage form according to claim 3 wherein said immediate release component comprises carbidopa and levodopa in a ratio of from about 1:1 to about 1:5.
18. A pharmaceutical dosage form according to claim 3 wherein said immediate release component comprises carbidopa and levodopa in a ratio of from about 1:1 to about 1:4.
19. A pharmaceutical dosage form according to claim 3 wherein said controlled release component comprises carbidopa and levodopa in a ratio of from about 1:1 to about 1:10.
20. A pharmaceutical dosage form according to claim 3 wherein said controlled release component comprises carbidopa and levodopa in a ratio of from about 1:1 to about 1:5.
21. A pharmaceutical dosage form according to claim 3 wherein said controlled release component comprises carbidopa and levodopa in a ratio of from about 1:1 to about 1:4.
22. A pharmaceutical dosage form according to claim 1 wherein said immediate release component exhibits an *in vitro* dissolution profile comprising at least about 10% levodopa release after 15 minutes and at least about 95% levodopa release after 1 hour.
23. A pharmaceutical dosage form according to claim 2 wherein said COMT inhibitor is selected from the group consisting of CGP-28014, entacapone, and tolcapone.

24. A pharmaceutical dosage form according to claim 1 wherein said dosage form further comprises one or more drugs selected from the group consisting of anti-cholinergics, beta 2-agonists, cyclooxygenase-2 (COX-2) inhibitors, dopamine receptor agonists, monoamine oxidase (MAO) inhibitors, opiate delta receptor agonists, opiate delta receptor antagonists, and N-methyl-D-aspartate (NMDA) antagonists.

25. A pharmaceutical dosage form according to claim 1 wherein said dosage form further comprises one or more drugs selected from the group consisting of albuterol, alpha-lipoic acid, amantadine, andropinirole, apomorphine, baclofen, biperiden, benztropine, bromocriptine, budipine, cabergoline, clozapine, deprenyl, dextromethorphan, dihydroergokryptine, dihydrolipoic acid, eliprotil, eptastigmine, ergoline, formoterol, galanthamine, lazabemide, lysuride, mazindol, memantine, mofegiline, orphenadrine, pergolide, pirbuterol, pramipexole, propentofylline, procyclidine, rasagiline, remacemide, riluzole, rimantadine, ropinirole, salmeterol, selegiline, spheramine, terguride, and trihexyphenidyl.

26. A pharmaceutical dosage form according to claim 3 wherein said immediate release component comprises from about 2.5 mg to about 75 mg carbidopa and from about 25 mg to about 300 mg levodopa.

27. A pharmaceutical dosage form according to claim 3 wherein said controlled release component comprises from about 2.5 mg to about 200 mg carbidopa and from about 25 mg to about 600 mg levodopa.

28. A pharmaceutical dosage form according to claim 3 wherein the controlled release component comprises from about 5 mg to about 150 mg carbidopa and from about 50 mg to about 500 mg levodopa.

29. A pharmaceutical dosage form according to claim 3 wherein the controlled release component comprises from about 12.5 mg to about 50 mg carbidopa and from about 50 mg to about 200 mg levodopa.

30. A pharmaceutical dosage form according to claim 1 wherein said dosage form is a particle.
31. A pharmaceutical dosage form according to claim 1 wherein said dosage form is a tablet.
32. A pharmaceutical dosage form according to claim 31 wherein said tablet is a layered tablet.
33. A method of treating a patient suffering from a pathology or disease characterized by reduced dopamine levels in the brain comprising the step of administering a pharmaceutical dosage form according to claim 1.